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26294 7590 10/09/2007 TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVEVLAND, OH 44114				
			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/973,609
Filing Date: October 09, 2001
Appellant(s): GABBAY, SHLOMO

MAILED 1

OCT 09 2007

Group 3700

Gary Pitzer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/27/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: the Examiner did not find where the Applicant called "the body portion **14**" out of the Office action. The Examiner was calling element **70** the body portion. Additionally, the Examiner was not calling **50** the cylindrical member as alleged by Applicant's arguments. The element was not labeled in Figs. 9,10 but as illustrated in the Office action by the Examiner it was clear that

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cylindrical member having a lumen was the device holding the plunger 60. The element labeled with reference numeral 50 was used by the Examiner as a referencing guide to show that the cylindrical member would have dimensions that were within the claimed range. Applicant also suggested that the plunger was not indicated as traversing the channel 50 which Applicant assumed the Examiner was interpreting this as the cylindrical member. However, as mentioned above, the Examiner did not consider the cylindrical member to be element 50 since it clearly did not have the prosthesis within it. The larger diameter tube holding the plunger was the cylindrical member of which the plunger did traverse part of it to urge the prosthesis from its opening as seen in Fig. 10.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,370,685	Stevens	12-1994
5,851,210	Torossian	12-1998
5,549,665	Vesely et al.	8-1996
6,077,296	Shokoohi et al.	6-2000
5,733,267	Del Toro	3-1998

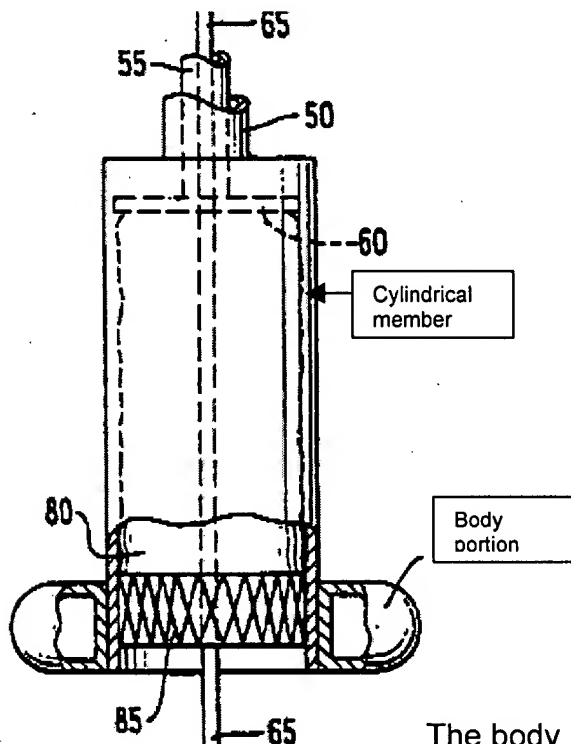
(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 21,28,51,61-63,67,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (5370685). Fig. 9 shows an implantation system with an

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elongate cylindrical member with an inner diameter that falls within the claimed range of 5-15mm since the inner channel 50 has dimensions as minimal as 0.5mm, the outer channel or cylindrical member would have dimensions clearly falling within the claimed range, col. 7, lines 65,66. It can also be seen there is a body portion as seen below.



The body portion and cylindrical member being coaxial and the body portion having a greater diameter than the cylindrical member. It can also be seen mounted within the system is a heart valve prosthesis with a generally cylindrical support **85** having a valve fixed between the ends of the support. Fig. 10 illustrates the system includes a plunger **60** to urge the prosthesis from the cylindrical member. Stevens discloses the valve can be natural tissue heart valve, col. 9, lines 7-13. Stevens also discloses the support structure can be made of shape memory like material, col. 9, lines 23-29. Figs. 11 & 12 show projections **90** biased to extend radially from the support. However, Stevens fails to disclose the cylindrical member extends to

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terminate in an opening spaced longitudinally apart from the body member. It would have been an obvious expedient to have the cylindrical member terminate apart from the body member such that it enables the surgeon to deliver the prosthesis to an area that is at a distance from the area where the delivery device can be stabilized for the surgeon to precisely place the implant. It is often difficult to stabilize the delivery catheter device where deployment occurs or at the opening of the cylindrical member, thus the provision of a stabilizing member at a distance or apart from the delivery opening can be advantageous such that it enables stabilization in a location of a vessel and the surgeon is provided with the precision necessary by not having the cylindrical member move.

Regarding claim 28, Stevens fails to disclose the use of a pulmonic valve. It would have been an obvious matter of design choice to modify the type of valve used, since applicant has not disclosed that using a pulmonic valve provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the type of valve chosen as taught by Stevens such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 28 because both heart valve prostheses perform the same function of being restrained in a first condition in a delivery device and then expanded into a second condition when implanted and provides a functioning valve replacement.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Torossian (5851210). Stevens is explained supra. However, Stevens

fails to disclose indicia on the cylindrical member. Torossian teaches (Fig. 2) indicia **54** are placed on the cylindrical member or catheter. Torossian additionally teaches the indicia are used to facilitate implantation of the device, col. 6, lines 26-28. It would have been obvious to one of ordinary skill in the art to incorporate indicia on the cylindrical member as taught by Torossian with the implantation system of Stevens such that it enables the surgeon to accurately place the valve in the location desired and know when it is at the implantation site by the use of the indicia.

Claims 22-26,65,66,68,69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Shokoohi et al. (6077296). Stevens is explained above. However, Stevens fails to disclose the support structure including biasing elements. Shokoohi et al. teaches (Fig. 2) an expandable prosthesis with a plurality of support features **54** joined by connecting element **56**. It can also be seen at the proximal and distal ends **55,59** that the projections extend radially outward and are triangular. Shokoohi also teaches that suture can be used to limit the outward expansion, col. 7, lines 32-39. Shokoohi also shows (Fig. 11) that the support features can have springs **60** at the ends for receiving the suture so sections attached will not separate. It would have been obvious to one of ordinary skill in the art to incorporate biasing elements as taught by Shokoohi with the prosthesis of Stevens such that it has enhanced securing means to hold a longer prosthesis together.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Vesely et al. (5549665). Stevens is explained supra. However, Stevens fails to disclose the use of a sheath to cover the exposed parts of the support. Vesely et

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al. teach to cover the exposed parts of the stent support (Figs. 2,4) using a sheath or covering **35**. It would have been obvious to one of ordinary skill in the art to use a sheath as taught by Vesely with the prosthesis of Stevens such that the stent support is covered to provide a smooth surface so no rigid structure can cause trauma to the surrounding tissue. Additionally, the sheath would prevent contact of the metal support with surrounding tissue and eliminate any possibility of irritation or allergic reaction to metal.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens '685 in view of Del Toro (5733267). Stevens is explained above. However, Stevens does not disclose a handle portion attached to the body of a cylindrical member for delivering the prosthesis. Del Toro teaches (Fig. 4) a handle **40** attached to the body of a cylindrical delivery device **32**. It would have been obvious to one of ordinary skill in the art to use a handle as taught by Del Toro with the delivery device of Stevens such that the surgeon can accomplish accurate control of the delivery device.

(10) Response to Argument

A) In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this instance, the inability often encountered by delivering valves to locations where it is difficult to stabilize the end of the delivery device one of ordinary skill in the art would look to modifying the delivery catheter and place the stabilizing member longitudinally spaced from the opening of where the valve is to be deployed. Such a simple adjustment of moving the "body member" or stabilizing member up along the length of the catheter or cylindrical member only involves routine skill in the art.

Applicant also argued that it was not obvious to substitute types of valves and use a pulmonic valve since Stevens mentions another type of valve. However, it appears the Applicant fails to appreciate that one of ordinary skill in the art would look to use an analogous type of valve to replace one that is defective. Stevens discloses a procedure to replace a valve other than the pulmonic and replace it with that same type of valve using a xenograft. Thus it would be within routine skill in the art to use a xenograft pulmonic valve to replace in a patient that has been found with a defective pulmonic valve.

B) Applicant argues that the combination of Stevens and Torossian is not proper. However, the teaching of Torossian clearly provides a motivation to one skilled in the art to incorporate indicia on a delivery device to provide the surgeon within the precision necessary to not cause injury to the patient by overextending or placing the device too far and damaging or puncturing tissue.

C) Applicant argues that Shokoohi and Stevens cannot be combined. However, as seen in Fig. 11 of Stevens a stent framework exists on the valve structure. It is within routine skill in the art to modify stent frameworks to increase the lengths required or add features to improve its structural stability and flexibility. Thus it would have been obvious to incorporate biasing elements of Shokoohi with Stevens's framework to provide more characteristics that increase its versatility.

D) Applicant again argues that the Examiner used hindsight reasoning for combining Stevens and Vesely. However, it is well known in the art that patients can have allergic reactions to implanted materials and thus adding a covering as taught by Vesely provides a smooth surface to contact the vessel wall and prevent potential irritation from the metal mesh framework and also prevent any unwanted tissue growth to occur into the valve device.

E) Applicant also argues it would not have been obvious to use a handle element as taught by Del Toro with the Stevens implantation system. However, Del Toro clearly teaches the handle device can be incorporated to control the use of the catheter while certain coaxial elements are being moved, col. lines 15-19. Thus one of ordinary skill in the art would desire a handle to deliver the prosthesis using the implantation system of Stevens and have the ability to move certain elements, i.e. the pusher element could be moved while the outer cylindrical member remains stabilized in place.

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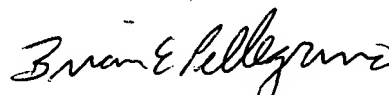
(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

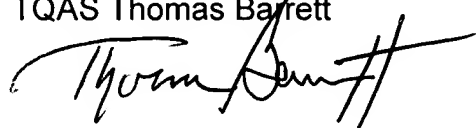
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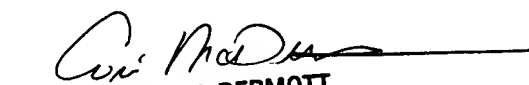
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